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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,757	04/14/2004	Yasufumi Kaneda	59150-8010.US00	7091

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EXAMINER
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WHITEMAN, BRIAN A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/824,757	KANEDA, YASUFUMI	
	<b>Examiner</b>	<b>Art Unit</b>	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-6, 8, 9, 11-14, 16, 18, 23, 25, 26, 30 is/are pending in the application.
- 4a) Of the above claim(s) 4, 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5, 6, 8, 9, 11-14, 16, 18, 23, 26 and 30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5/1/06, 1/26/06</u>   | 6) <input type="checkbox"/> Other: _____                                    |

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## **DETAILED ACTION**

### **Non-Final Rejection**

Claims 1, 2, 4-6, 8, 9, 11-14, 16, 18, 23, 25, 26, and 30 are pending.

Applicant's traversal, the amendment to the specification, the cancellation of claims 3, 7, 20-22, 24, 27-29, 31, and 32, the amendment to claims 1, 5, 13, 14, 16, and 18 filed on 5/1/06 is acknowledged and considered.

### ***Election/Restrictions***

Claims 4 and 25 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/24/06.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 5, 6, 8, 9, 11, 12, 13, 14, 16, 18, 23, 25, 26, and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 5, 6, 8, 9, 11, 12, 13, 14, 16, 18, 223, 25, 26, and 30 recite the limitation "the virus is inactivated" in line 2 of claim 1. There is insufficient antecedent basis for this limitation in the claims. It is not defined if the limitation is referring to the virus envelope or the gene transfer vector.

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Claims 1 and claims dependent therefrom are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: inactivating the genome of a herpes virus. The skilled artisan understands that you can inactivate a virus by deleting at least part of the genome. But, it is unclear to the skilled artisan how to inactivate the genome of the virus.

Claims 2, 5, 6, 8, 9, 13, 14, 16, 18, 23, 26, and 30 recite the limitation "the virus". There is insufficient antecedent basis for this limitation in the claim. This lack of antecedent basis makes it unclear in determining the structure of the claimed invention. Does the claim define adding an exogenous gene to an existing viral particle or making a viral genome that comprises an exogenous gene and then packaging the genome to form a virus?

Claim 9 recites the limitation "detergent is octylglucosidase" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claims 18 and 30 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: steps for preparing the gene transfer vector.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The limitation “for introducing a gene into animal in vivo tissue” in claims 11 and 12 does not have patentable weight over the prior art. See MPEP 2111.

The limitation “kit for screening gene libraries” in claims 14 and 26 does not have patentable weight over the prior art. See MPEP 2111.

The limitation “pharmaceutical” in claims 13 and 25 does not have patentable weight over the prior art. See MPEP 2111.

Claims 1 and claims dependent therefrom (claims 2, 5, 6, 8, 9, 11, 12, 13, 14, 23, and 26 read on a virus comprising a viral vector comprising an exogenous gene.

Claims 5, 6, and 8-9 are directed to a product by process. Thus, if the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The product in claims 5, 6, 8 and 9 read on a replication defective herpes virus comprising a gene transfer vector comprising an exogenous gene.

Claims 1, 2, 5, 6, 8, 9, 11, 12, 13, 14, 23, and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Epstein et al. (US 6,183,752). Epstein teaches a replication defective herpes virus comprising an expression vector comprising an exogenous DNA (column 1).

Applicant's arguments, see page 8, filed 5/1/06, with respect to the rejection(s) of claim(s) 1-3, 5, 11-14, 16, 18, 23, 24, 26, 27, 30 and 31 under 102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the amendment to claim 1.

Claims 1, 2, 5, 6, 8, 9, 11, 12, 13, 14, 18, 23, 26, and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Altieri (US 6509162). Altieri teaches producing a replication defective herpes virus comprising a transgene and delivering to an ex vivo cell (column 19 and 20).

Applicant's arguments, see page 8, filed 5/1/06, with respect to the rejection(s) of claim(s) 1-3, 5, 11-14, 16, 18, 23, 24, 26, 27, 30 and 31 under 102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the amendment to claim 1.

Claims 1, 2, 5, 6, 8, 9, 11, 12, 13, 14, 18, 23, 26, and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Fong et al. (US 6051428). Fong teaches a replication defective herpes virus comprising a transgene (column 1). Fong teaches administering Triton X-100 to an isolated cell infected with the replication defective herpes virus (column 24).

### ***Response to Arguments***

The Declaration under 37 CFR 1.132 filed 5/23/06 is sufficient to overcome the rejection of claims 1, 2, 5-7, 11-5, 18, 20, 23, 26, and 30 based upon 102(e) over Hoon et al. (US

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6432,925). The Declaration shows that Mr. Kaneda conceived or invented the subject matter disclosed in '925.

The Declaration under 37 CFR 1.132 filed 5/1/06 is sufficient to overcome the rejection of claims 1, 2, 5-7, 11-5, 18, 20, 23, 26, and 30 based upon 102(e) over Hoon et al. (US 672375). The Declaration shows that Mr. Kaneda conceived or invented the subject matter disclosed in '375.

Applicant's arguments, see terminal disclaimer, filed 5/1/06, with respect to provisional obviousness double patenting and obviousness double patenting rejection have been fully considered and are persuasive. The rejection of 1, 2, 5-9, 11-14, 16, 18, 20-23, 26, 29 and 30 has been withdrawn because the cancellation of claims 7, 20-22, and 29 and the filing of a terminal disclaimer over the applications 11,126,770 and 10/485,752 and US patent '923.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, SPE – Art Unit 1635, can be reached at (571) 272-4517.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (571) 273-8300.

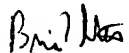
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman



**BRIAN WHITEMAN  
PATENT EXAMINER**